

Multicentre case-control study evaluating the safety of anti-SARS-CoV-2 vaccines in a cohort of patients with systemic vasculitis

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Abstract

Objective

Data on the safety of anti-SARS-CoV-2 vaccines in patients with rare rheumatic diseases, such as systemic vasculitis (SV), are limited. The aim of this study was to evaluate the occurrence of a disease flare and the appearance of adverse events (AEs) following administration of anti-SARS-CoV-2 vaccine in a multicentre cohort of patients with SV.

Methods

Patients with SV and healthy controls (HC) from two different Italian rheumatology centres were asked to complete a questionnaire assessing disease flares occurrence, defined as new onset of clinical manifestations related to vasculitis needing an implementation of therapy, and local/systemic AEs appearance following anti SARS-CoV-2 vaccination.

Results

107 patients with SV (57 ANCA-associated) and 107 HC were enrolled. A disease flare occurred in only one patient (0.93%) with microscopic polyangiitis after the first dose of an mRNA vaccine. After both the first and the second vaccine dose administration, no significant differences in AEs between patients with SV and HC were observed; no serious AEs were reported as well.

Conclusion

These data suggest a good risk profile for anti-SARS-CoV-2 vaccine in patients with systemic vasculitis.

Key words

systemic vasculitis, vaccination, SARS-CoV-2, adverse events, disease flare

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Introduction

Systemic vasculitis (SV) is a group of rare rheumatic diseases characterised by the primary inflammation of blood vessel walls and a large spectrum of systemic manifestations, in some cases with potential life-threatening complications (1, 2). Due to the disease itself or the ongoing immunosuppressive treatment (*i.e.* rituximab), patients with systemic vasculitis seem more prone to develop infections (3). At the end of 2019, the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), a new, single positive-stranded RNA coronavirus identified in Wuhan, China, that can lead to a severe respiratory syndrome in humans, began spreading worldwide causing the Coronavirus disease 2019 (COVID-19) pandemic (4). Patients with rare rheumatic diseases such as systemic vasculitis, especially older than 35 years, seems to be at higher risk of death caused by COVID-19 compared to healthy subjects and other rheumatic musculoskeletal disorders (5, 6). By the end of 2020 different vaccines against SARS-CoV-2 infection have been developed and they quickly became one of the most important tools in preventing virus spreading and the development of fatal complications. Considering the higher risk to develop more aggressive forms of COVID-19, patients with systemic rheumatic diseases were prioritised in the vaccination campaigns. Over the last two years, some studies evaluated the efficacy and safety of anti-SARS-CoV-2 vaccines in patients with systemic rheumatic diseases with evidence of an acceptable safety profile and a lower immunogenicity compared to the healthy population (7, 8). However, data concerning patients with systemic vasculitis are still limited. This retrospective case-control study aimed at evaluating the safety of SARS-CoV-2 vaccines in a large multicentre cohort of patients with systemic vasculitis with a particular focus on disease flares occurrence and the development of local and systemic adverse events (AEs) following vaccination.

Materials and methods

Patient enrolment

After providing consent to participate, patients diagnosed with SV undergoing

SARS-CoV-2 vaccination were retrospectively enrolled at the Rheumatology Units of the University of Rome Sapienza and the University of Siena, Italy. Inclusion criteria included a follow up within 6 months before the administration of at least one dose of an anti-SARS-CoV-2 vaccine (Comirnaty-BNT162b2, Spike Vax-mRNA-1273 or Vaxzevria-ChAdOx1-S). The main demographic, clinical and therapeutic features were collected on a dedicated electronic database. Healthy subjects were recruited among members of the healthcare staff of the University Hospital Policlinico Umberto I in Rome, Italy and used as controls (HC).

The study complies with the Declaration of Helsinki. The Local Ethical Committee has approved the research (Sapienza Università di Roma Ethical Committee - protocol 0501/2021). All the subjects gave their informed consent to use their anonymised data for the study.

Questionnaire administration

After at least two and within four months after the last dose of vaccine patients with SV and HC were asked to complete a questionnaire evaluating the following items: 1) previous diagnosis of SARS-CoV-2 infection; 2) complete two doses cycle of anti-SARS-CoV-2 vaccination; 3) type of vaccine; 4) occurrence of a disease flare following vaccination; 5) occurrence of AEs following vaccination; 6) time to the AEs (days); 7) type of AEs defined as local and/or systemic; 8) ongoing treatment; 9) withdrawal of therapy prior to vaccination. The questionnaire was proposed during a follow-up visit or by means of a telephone call.

A previously used definition of disease flare was adopted: new onset of signs and symptoms related to vasculitis lasting at least 2 days and occurring within 2 months from the last dose of vaccination requiring treatment modifications (9). AEs were defined as local, in case of occurrence of reaction in the site of injection (pain and/or swelling and/or redness and/or itching), or systemic, in case of occurrence of one of the following symptoms: anaphylaxis, fever, arthromyalgia, fatigue, malaise, lymphadenopathy and others as specified

Competing interests: none declared.

Table I. Demographic and clinical features of subjects participating to the study.

	Vasculitis n=107	HC n=107
Age, median years (1 st Qu., 3 rd Qu.)	68 (56, 77)	63 (60, 68.5)
Female, n° (%)	67 (62.6)	62 (57.9)
Previous SARS CoV2 infection, n° (%)	8 (7.4)	5 (4.6)
Vaccine type, n° mRNA - n° viral vector	102 - 5	92-15
AAV, n (%)	57 (53.3)	-
GCA, n (%)	44 (41.1)	-
PAN, n (%)	4 (3.73)	-
TAK, n (%)	2 (1.86)	-
Ongoing therapy with immunosuppressors, n (%)	81 (75.7)	-
Prednisone or equivalent only, n (%)	7 (6.5)	-
csDMARDs, n (%)	36 (33.6)	-
bDMARDs, n (%)	37 (34.5)	-
rituximab, n (%)	19 (17.7)	-
anti-IL-6, n (%)	17 (15.8)	-
mepolizumab, n (%)	1 (0.93)	-
tsDMARDs, n (%)	1 (0.93)	-
Therapy withdrawal before vaccination, n (%)	15 (14)	-

AAV: ANCA-associated vasculitis; bDMARDs: biologic disease modifying anti-rheumatic drugs; cs-DMARDs: conventional synthetic disease modifying anti rheumatic drugs; GCA: giant cell arteritis; HC: healthy controls; IL-6: interleukin 6; PAN: polyarteritis nodosa; Qu: quartile; TAK: Takayasu's arteritis; tsDMARDs: target synthetic disease modifying anti-rheumatic drugs.

by the patients among which headache, diarrhoea, dizziness; systemic symptoms were selected among those more frequently reported in the literature (7, 8, 10). Prior infection was defined as a reported positivity to a nasopharyngeal swab for SARS-CoV-2.

Statistical analysis

Medians and interquartile ranges or frequencies and proportions were reported for continuous or categorical variables, respectively. Mann-Whitney and Chi-square tests were used to compare the statistical significance of differences in

the distribution of continuous or categorical variables, respectively, between SV and HC. To account for baseline clinical differences among SV and HC, multivariable logistic regression analysis was used to assess the impact of the presence of SV on the above-mentioned items. Covariates were selected according to a clinical criterion and included age and sex. Kaplan-Meier method was used to evaluate the 7-day survival rate, meaning as survival the intercurrent period between vaccine administration and AEs appearance. All statistical tests were performed using the RStudio graphical interface v. 0.98 for R software environment v. 3.0.2. All tests were two-sided with a significance level set at $p < 0.05$.

Results

Features of enrolled patients with systemic vasculitis and HC

We selected 107 patients with SV (women n=67, men n=40) and 107 HC (women n=62, men n=45), with a median age of 68 (1st Qu. 56, 3rd Qu. 77) and 63 (1st Qu. 60, 3rd Qu. 68.5) years, respectively. Among the SV group, 57 were ANCA-associated vasculitis (AAV): 22 granu-

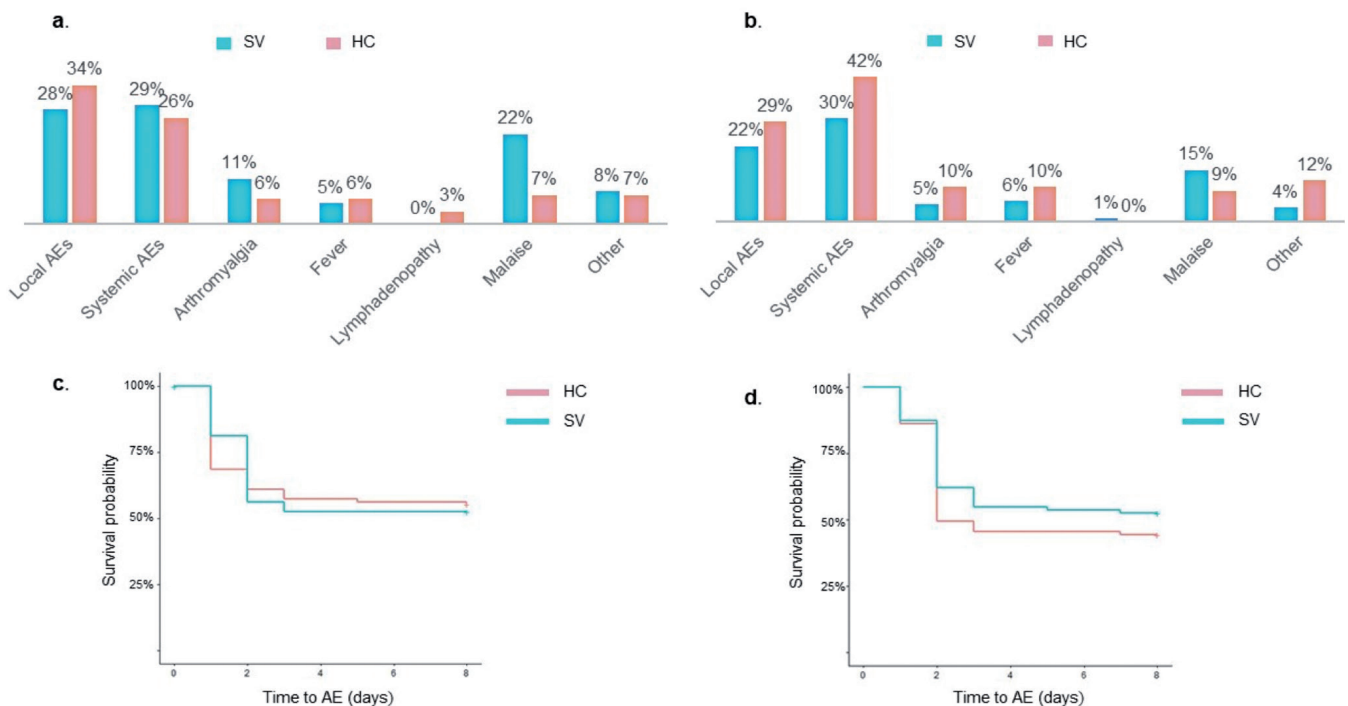


Fig. 1. Frequency of local and systemic AEs after the first (a) and the second dose (b). Survival curves of AEs in patients with SV and HC after the first (c) and second dose (d). AEs: adverse events; HC: healthy controls; SV: systemic vasculitis.

lomatosis with polyangiitis (GPA), 16 eosinophilic granulomatosis with polyangiitis (EGPA), 19 microscopic polyangiitis (MPA). Forty-four patients had giant cell arteritis (GCA), 4 polyarteritis nodosa (PAN) and 2 Takayasu's arteritis (TAK). In SV cohort, 96 patients received two doses of anti-SARS-CoV-2 vaccine while 8 patients received only one dose of the vaccine due to SARS-CoV-2 infection occurred prior to vaccine or after the administration of the first dose and 3 patients refused to receive the second dose. No patient refused to participate with a response rate of 100%. The main demographic, clinical and therapeutic features of enrolled patients and HC are reported in Table I.

In patients with SV the occurrence of a disease flare following anti-SARS-CoV-2 vaccination is a rare event

A disease flare following vaccination with Comirnaty-BNT162b2 vaccine was detected in only one case of SV. Specifically, this patient was a 77-year-old male with a diagnosis of MPA treated with methotrexate. This patient developed a pulmonary disease flare seven days after the first dose of the vaccine, the flare started as a moderate-severe dyspnoea and evolved into respiratory failure leading to patient's hospitalisation. Nasopharyngeal swabs for SARS-CoV-2 were negative. Diffuse "ground-glass" opacities with superimposed septal thickening and subpleural consolidations emerged at the high-resolution computed tomography. During hospitalisation, the patient required high-flow oxygen and was treated with high dose intravenous glucocorticoids with benefit. Details on clinical and laboratory features of this patient were recently described in our previous publication (11).

AEs following SARS-CoV-2 vaccination are similar between patients with SV and HC

The proportion of AEs is reported in Figure 1a-b. Following the first and the second dose administration of anti-SARS-CoV-2 vaccine, no significant differences in AEs were detected between patients with SV and HC (first

Table II. Risk of AEs in patients with SV and HC.

ENTIRE COHORT					
Adverse events (first dose)			Adverse events (second dose)		
	OR	p-value		OR	p-value
Clinical condition					
SV	1.11 (0.63-1.95)	0.708	SV	0.70 (0.39-1.24)	0.226
HC	Ref	-	HC	Ref	-
Age and sex					
Age	0.95 (0.92-0.97)	0.0002	Age	0.96 (0.93-0.98)	0.001
Female	1.51 (0.85-2.68)	0.154	Female	1.39 (0.77-2.51)	0.262
Male	Ref	-	Male	Ref	-
SYSTEMIC VASCULITIS					
Adverse events (first dose)			Adverse events (second dose)		
	OR	p-value	OR	p-value	
Ongoing therapy with immunosuppressor (IS)					
IS	1.62 (0.63-4.13)	0.307	IS	0.94 (0.36-2.45)	0.905
No IS	Ref	-	No IS	Ref	-
Category of immunosuppressive drugs					
bDMARDs	1.52 (0.53- 4.34)	0.433	bDMARDs	1.04 (0.35-3.02)	0.942
csDMARDs	1.78(0.61 – 5.21)	0.283	csDMARDs	0.79 (0.25-2.40)	0.678
Prednisone only	1.44 (0.25 – 8.06)	0.676	Prednisone only	1.24 (0.20-7.65)	0.815
None	Ref	-	None	Ref	-
Withdrawal of immunosuppressive therapy					
Withdrawal	0.48 (0.14-1.59)	0.236	Withdrawal	0.44 (0.12-1.59)	0.215
No withdrawal	Ref	-	No withdrawal	Ref	-

AEs: adverse events; bDMARDs: biologic disease-modifying anti-rheumatic drugs; csDMARDs: conventional synthetic disease modifying anti rheumatic drugs; HC: healthy controls; IS: immunosuppressors; OR: odds ratio; SV: systemic vasculitis; tsDMARDs: target synthetic disease-modifying anti-rheumatic drugs.

dose: OR=1.11 IC 0.63-1.95, $p=0.708$; second dose: OR=0.70 IC 0.39-1.24, $p=0.226$) (Table II). In both groups, higher age was associated with a reduced risk of developing AEs (Table II); the frequency of AEs according to different age groups is shown in Figure 2a-b. Both in the SV group and in the HC group, the survival analysis demonstrated a major occurrence of AEs within 1-2 days from vaccine administration (Fig. 1c-d). All reported AEs were mild with malaise and arthralgia being the most frequently reported in the group of patients with SV; no systemic anaphylaxis and no severe AEs were reported in both groups. No significant differences in AEs occurrence were detected according to the ongoing therapy (Table II).

Discussion

This is one of the largest studies investigating the occurrence of disease flares

and AEs in patients with SV following SARS-CoV-2 vaccination in a real-world setting.

It is well known that immunological stimuli, including vaccines administration, may trigger, in limited cases, a disease flare up in patients with rheumatic diseases (12). The occurrence of disease flares in our cohort was very low with evidence of only one case out of 107 patients. Even though this flare was severe, and the patient was hospitalised, he was discharged after one week in good clinical conditions. Our findings, together with the previous demonstration in GCA patients of no significant difference in the rate of flares between patients receiving vaccination for influenza virus and patients receiving vaccination for SARS-CoV-2 (13), look extremely encouraging. A great efficacy of SARS-CoV-2 vaccination has been demonstrated in the general population (14, 15) and our data,

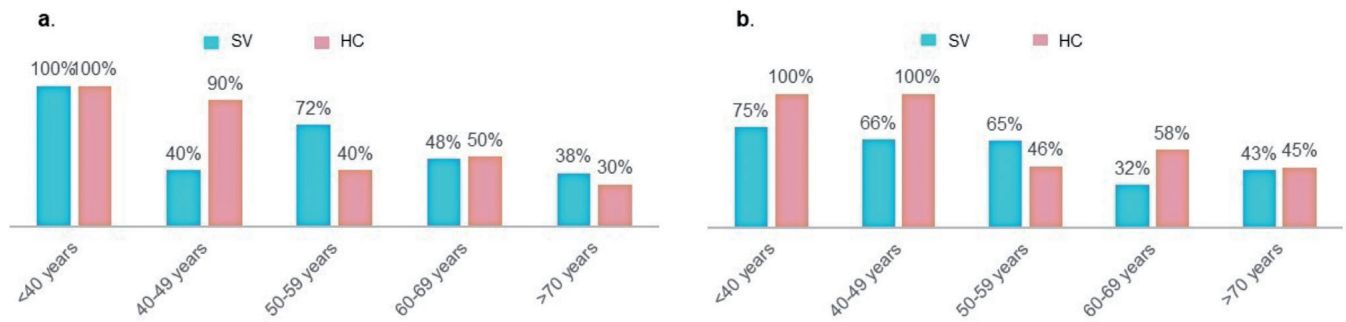


Fig. 2. Frequency of local and systemic AEs after the first (a) and the second dose (b) in SV and HC divided by decades. AEs: adverse events; HC: healthy controls; SV: systemic vasculitis.

along with previous evidence (13, 16), supporting the safety of these vaccines in SV patients further encourage their administration both to protect from possible life-threatening complications of COVID-19 and to prevent virus spreading.

In our study the frequency of AEs was similar between patients and controls and generally mild in all of them. In the SV group, no association was found between the ongoing immunosuppressive therapy and the risk of developing AEs. Consistent with our previous findings (17), and as reported in RCTs (14, 15), an inverse association between AEs occurrence and patients' age has been detected. Specifically, a higher age appears as associated with a lower risk of developing AEs; this finding is not surprising as immunosenescence is known to contribute to a reduced vaccine response in older patients and, eventually, a lower occurrence of AEs (18).

Our findings are in line with previous studies demonstrating a low rate of disease flare and an overall good risk profile in patients with rheumatic diseases (8, 10, 13). Interestingly, in one of these studies a lower occurrence of disease flare was observed in patients with connective tissue diseases and vasculitis compared to other rheumatic conditions such as inflammatory joint diseases (10). Thus, the similar tolerance profile of these vaccines between patients with SV and HCs, as well as the rarity of disease flares, is a reassuring result useful for physicians to encourage patients with SV to undergo vaccination. This topic is particularly relevant as a remarkable vaccine hesitancy has been documented in our patients during COVID-19 pandemic

(19). The possibility that anti-SARS-CoV2 vaccination might induce the new appearance of a SV is fearsome. It is interesting to note that new cases of SV have been documented following anti-SARS-CoV-2 vaccination. We had the opportunity to describe the onset of leukocytoclastic vasculitis following anti-SARS-CoV-2 vaccination with Vaxzevria-ChAdOx1-S (20) and there are a few case reports demonstrating the new appearance of ANCA-associated vasculitis as well as IgA vasculitis and GCA after the administration of anti-SARS-CoV-2 vaccines (21-25). These observations provide interesting insight on the pathogenesis of SV and will surely deserve further investigations. However, whether the link between COVID-19 vaccine and autoimmune manifestations occasionally described is coincidental or causal remains to be clarified and the overwhelming benefits of mass anti-SARS-Cov-2 vaccination in preventing COVID-19 morbidity and mortality is unquestionable.

This study has some limitations, specifically, its retrospective nature did not allow to calculate the exact disease activity at the time of vaccination. However, as suggested by currently available recommendation on vaccine administration in patients with rheumatic diseases (26-29), vaccines should be administered preferentially in patients with inactive disease (29). As included SV patients were strictly monitored in our dedicated outpatient clinics, they were vaccinated only if the referring physician considered them in an inactive phase of disease. Another limitation of the study is the possible occurrence of recall bias in patients' answers regarding AEs, although the question-

naire was proposed to them in the period immediately following vaccine administration.

Being SV a rare disease, strength of this study is represented by the large sample size and by its case-control nature. Additionally, its multicentre nature allowed us to include different types of SV referring to two major dedicated rare disease clinics in our country.

Conclusions

To conclude, this is one of the largest studies investigating the safety of anti-SARS-CoV-2 vaccines in patients affected by SV. Taken together, our data strongly support a relatively good safety profile of anti-SARS-CoV-2 vaccines in patients with SV and encourage physicians in recommending anti SARS-CoV-2 vaccination in patients affected by this rare rheumatic disease.

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